REMARKS

The Office Action dated February 26, 2007 has been received and carefully studied.

A Request for Continued Examination is filed herewith.

The Examiner maintains the rejection of claims 1 and 3-8 under 35 U.S.C. §103(a) as being unpatentable over Yokoyama in view of Matsumara and in view of JP-A-2001-226294, and as being unpatentable over Sakurai et al. in view of Matsumara and in view of JP-A-2001-226294. The Examiner The Examiner states that Yokoyama discloses that the solvent used can be DMF, dioxane, THF, water of a mixture thereof, and that water/THF would satisfy the claimed mix of water and a low-boiling point organic solvent. The Examiner notes that although Matsumara points out problems with dialysis and ultrafiltration, Matsumara was only cited for its teaching that it would be obvious to use another technique to concentrate drugs instead of ultrafiltration and dialysis, and JP '294 was cited to show that producing a macromolecular block copolymer-drug composite by steps other than dialysis or ultrafiltration was known. Regarding the latter rejection, the Examiner argues that Matsumara discloses that when dialysis or ultrafiltration are conducted on pharmaceuticals with contained drugs, part of the drug is also removed, and thus it does not matter that Sakurai does not encapsulate the drug in its core.

By the accompanying amendment, the low boiling-point organic solvent miscible with water has been restricted in claims 1 and 8 to methanol, ethanol, isopropanol or acetone. Support for the amendment can be found on page 10, lines 5-7 of the

specification.

Yokoyama discloses the preparation method of a high molecular block copolymer-drug complex pharmaceutical preparation, wherein the high molecular block copolymer is dissolved in a solvent. It provides as examples of the solvents to be used DMF, DMSO, dioxane, THF, water, a mixture solvent thereof, and states that DMF or a solvent of DMF and water is preferred (column 12, lines 52-60). After the dimer, trimer or tetramer of anthracycline compound is added to the solution, the solvent of the mixture solution is replaced with water by means of dialysis, ultrafiltration or the like.

According to the claimed invention, a mixed solvent of water and a specific low boiling-point organic solvent miscible with water selected from methanol, ethanol, isopropanol and acetone is used to dissolve an AB type block copolymer composed of hydrophilic polymer structure moiety and hydrophobic polyamino acid structure moiety together with a drug, thereby the conventional methods such as dialysis and ultrafiltration are eliminated. Consequently, the claimed invention provides the advantageous effect that a drug to be added is not lost in the course of the production operation, and consequently a drug is not wasted and the ratio of capsulation of a drug in the block copolymer can be enhanced (page 11, line 4 from the bottom to page 12, line 1). The remarkable effect of the claimed invention over the prior art is clearly illustrated in the working examples.

It is evidence that Yokoyama neither discloses nor suggests

the use of the specific solvents defined in the amended claim 1. Further, the process disclosed in Yokoyama essentially involves dialysis and/or ultrafiltration. Accordingly, the process for producing a block copolymer-drug composite of the present invention, wherein a mixed solvent of water and methanol, ethanol, isopropanol or acetone is used, and neither a dialysis nor an ultrafiltration process is included in the production process, is not obvious over Yokoyama.

JP-A-No. 2001-226294 (hereinafter referred to as '294) uses water immiscible organic solvent (refer to claim 1 of '294). In contrast, methanol, ethanol, isopropanol and acetone used in the claimed invention are water miscible organic solvents, which are neither disclosed nor suggested in '294. Accordingly, the process for producing a block copolymer-drug composite of the present invention, wherein a mixed solvent of water and methanol, ethanol, isopropanol or acetone is used, is not obvious over a combination of Yokoyama and '294.

Further, the preparation process of '294 is characterized in that it comprises the steps of forming an oil-in-water emulsion with water immiscible organic solvent and water, subsequently removing the organic solvent by distillation (refer to claim 1 of '294). Since DMF, DMSO, dioxane and THF disclosed in Yokoyama are water miscible organic solvents, they cannot form with water an oil-in-water emulsion, so that the preparation method of '294 cannot be applied to Yokoyama. Thus, those skilled in the art would not be motivated to combine Yokoyama with the preparation method of '294. Accordingly, the process for producing a block

copolymer-drug composite of the present invention, wherein a mixed solvent of water and methanol, ethanol, isopropanol or acetone is used, and neither a dialysis nor an ultrafiltration process is included in the production process, is not obvious over Yokoyama in view of '294.

Matsumara does not supply the above-described deficiencies of Yokoyama and '294.

Sakurai is directed to a preparation method wherein DMF/water is used, and dialysis and ultrafiltration are conducted. In contrast, the present invention is directed to the process for producing a block copolymer-drug composite of the present invention, wherein a mixed solvent of water and methanol, ethanol, isopropanol or acetone is used, and neither a dialysis nor an ultrafiltration process is included in the production process. Accordingly, the present invention as now claimed is not disclosed or suggested by Sakurai.

In addition, since DMF/water cannot form an oil-in-water emulsion, the preparation method of '294 cannot be applied, and Sakurai cannot be combined with '294.

Matsumara does not supply the above-described deficiencies of Yokoyama and '294.

Reconsideration and allowance are respectfully requested in view of the foregoing.

Respectfully submitted,

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